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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/295,302	04/21/99	SCHMIDT	K 000007.00148

002779 HM12/0329
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EXAMINER	
GUPTA, A	
ART UNIT	**PAPER NUMBER**
1653	15

DATE MAILED: 03/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/295,302	Schmidt
Examiner	**Group Art Unit**
ANISH GUPTA	1653

☒ Responsive to communication(s) filed on *Jan 4, 2001*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *8-33* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *8-33* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The amendment filed 1-4-01 is acknowledged. Claims 1-7 were canceled in the amendment and claims 8-33 were added. Clams 8-33 are pending in this application.

2. All rejections made in the previous office action are withdrawn since Applicant canceled claims 1-7. An office action on claims 8-33 follows below.

Claim Rejections - 35 USC § 112
Second Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites "structural component", "recruiting component", and "growth and/or maturation component." However, it is unclear as to what constituents comprise each of the components.

In claim 31-33, it is stated that the "carrier is in the form of a body". However, it is unclear what this "body" is suppose to be. Since the definition is unclear, the claims are indefinite.

First Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 33-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of stimulating the formation of bones, does not reasonably provide enablement the reproduction of

bone and production of bones. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable the invention commensurate in scope with these claims.

The claims are drawn to a means for production or reproduction of bones or vertebral structures. The claims are broad enough to read on the reproduction of bones spontaneously. The specification, however, fails to provide ample guidance on the production and reproduction of bones spontaneously. The specification providence guidance as to the acceleration of bone growth of existing bones after defects. The disclosure, however, fails to provide any guidance, in the way of working examples or literal disclosure, of how the active ingredient complex can be used for the production or reproduction of bone in an individual, once administered to the individual. It is well known in the art that bones do not grow spontaneously and thus a method of reproduction or production of bones spontaneously would not be enabled. As stated above, the claims do not recite that the complex is implanted on a defective or broken bone. Rather the claims state that the administration of the complex would lead to the "production or reproduction of bone," implying that missing bones automatically regenerate. Applicants specification is similar to the disclosure discussed in *Ex parte Sudilovsky*, [sic] 21 U.S.P.Q2d 1702 (BPAI 1991) where it was held that the disclosure was non-enabling since:

> "[t]he specification, though highly detailed, is devoted solely to a description of compounds stated to be known ACE inhibitors. The remainder of the specification is directed to how to make tablets and solutions for injection. Any disclosure regarding utility is confined to broad allegations and suggestions without substantiating working example. As stated in In re Glass, 492 F.2d 1228, 181 USPQ 31, 35 (CCPA 1974), 'the strong feeling one gets from reading the entire specification is that either appellant did not have possession of the details of a single operative process or, if he did, he chose not to divulge them.'"

Similarly, Applicants specification discloses compositions that can be used for the acceleration bone defects in existing bones. However, the disclosure, with regard to method of producing or reproducing bones, spontaneously, is confined to broad allegations and suggestions without substantiating working examples. Although working examples are not necessary in the specification, lack of a working example, however, are a factor to be considered. When a patent applicant chooses to forego exemplification and bases utility on broad terminology and general allegations, he runs the risk that unless one with ordinary skill in the art would accept the allegations as obviously valid and correct, the examiner may, properly, ask for evidence to substantiate them. *In re Novak*, 306 F.2d 924, 134 USPA 335 (CCPA 1962) 4; *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971). In this case, the disclosure has not provided

evidence of record of compositions that could be utilized to reproduce organs and the art has indicated that at least one organ, CNS neurons, do not regenerate, undue experimentation would be required to practice the claimed invention.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 8-14 and 31 are rejected under the judicially created doctrine of double patenting over claims 1-8 of U. S. Patent No. 5,932,207 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

The claims of the instant application are drawn to a composition comprising carrier and an active ingredient comprising at lease one bone derived structural component, at least one bone derived recruiting component, at least one bone derived adhesion component, and at lease one bone derived growth and/or maturation component. The claims further specify that the carrier is a polymer, ceramic, metallic or nonmetallic material. The claims of the US Patent are drawn to a complex for the growth of bony tissue or bone comprising a structural component, chemotactic component for recruiting bone growth cells, bone derived adhesion component, and a bone derived growth factor (see claim 1). The chemotactic component is a recruiting component of the instant application since both have an identical species group (see page 1 of the specification and the paragraph bridging 4 and 5 of the US patent). The US patent further states that the structural component can also include a metallic, ceramic, vitreous, polymeric and fatty carrier to aid in the modification of the structural component (see col. 3, lines 65-67 and col. 4, lines 1-5). Thus the claims, when reciting structural component, would include the carriers claimed.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

9. Claims 8-12, 14-26, 31-33 are rejected under the judicially created doctrine of obviousness-type·double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,830,859 in view of Harle and Samchukov et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims of the instant application are drawn to a production or reproduction of biological parts by using a complex comprising on structural component, recruiting component, adhesion component, and a growth and/or maturation component. Note that the recruiting component is defined as a chemotactic substance (page 1 of the instant specification).

The claims of the US Patent claims a method of stimulating the formation of bone in a maxillary sinus by utilizing a composition comprising a bone derived protein complex with some chemotaxis component, bond derived structural and adhesive component, and a bond derived growth or maturation component. The components claimed in the US Patent are similar to the components claimed in the instant application. The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of osteoporosis, bone defects etc. . . However, since the US Patent claims that the composition is useful for the stimulating bone formation, it would have been obvious the composition could be used for the treatments claimed in the instant applications. The difference between the prior art and the instant application is that the US Patent does not teach the use of a carrier that is a polymer, ceramic, metallic or nonmetallic material.

However, it is well known in the art that materials such as hydroxylapatite, titanium, aluminum oxide all have bone strengthening activity. For example, Harle, teaches a composition comprising hydroxylapatite, titanium, or aluminum oxide to make artificial bone materials (see col. 5, lines 45-60 and col. 6, lines 11-32). Similarly, Samchukov et al. teach that hydroxylapatite, titanium, aluminum oxide can be used as carriers in a device that enhances the shape and strength of bone (see col. 2, lines 61-67, col. 3, lines 65-67 and col. 4, lines 1-27). Therefore, it would

have been obvious to use the carriers claimed because all can be used for strengthening bone. Further, it has been held that combination of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, it would have been obvious to combine the carriers such as hydroxylapatite, titanium or aluminum with the composition of the US Patent because both are individually taught to be used for bone strengthening.

10. Claims 8, 9 13-14, 15-16, and 27-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,830,859 in view of Meuli et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims of the instant application are drawn to a production or reproduction of biological parts by using a complex comprising on structural component, recruiting component, adhesion component, and a growth and/or maturation component. Note that the recruiting component is defined as a chemotactic substance (page 1 of the instant specification).

The US Patent has been discussed supra. The difference between the US Patent and the instant application is that the US Patent does not disclose the use of a carrier such as polylactate.

However, both references of Lyle et al. And Meuli et al. teach the use of Polylactate in a prosthesis. Meuli states that polylactate can be used to provide stability of the prosthesis until new bone has come in (see col. 1, lines 63-68). Therefore it would have been obvious to use Polylactate in the composition because polylactate provides stabilization of a prosthesis until new bone has grown.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

Christopher S.F. Low

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